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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,866	STERN ET AL.	
	Examiner	Art Unit	
	Unsu Jung	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16,20,25-36,38-50 and 52* is/are pending in the application.

4a) Of the above claim(s) *10,14,26-36,38-50 and 52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-13,16,20 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/9/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendments in the reply filed on October 9, 2007 have been acknowledged and entered. The following amendments in reply have been entered:

- amendments to claims 1, 3, 4, 8, 11, 16, 20, and 25; and
- cancellation of claims 15, 17-19, 21-24, 37, and 51.

2. The typo noted by the Applicant in the item 2 of the previous Office Action dated April 9, 2007 has been acknowledged. As correctly noted by the Applicant, claims 24 and 25 are indicated as being both withdrawn and under consideration. Claim 24, which is now canceled, had been previously withdrawn as a result of Restriction requirement dated November 29, 2006 and should have been indicated as being withdrawn, not under consideration. Claim 25 should have been indicated as being under consideration and not withdrawn.

Claims 1-14, 16, 20, 25-36, 38-50, and 52 are pending, claims 10, 14, 26-36, 38-50, and 52 have been withdrawn, and claims 1-9, 11-13, 16, 20, and 25 are under consideration for their merits.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on October 9, 2007 has been considered by the examiner. However, the missing page number (pp1018-1030)

for Chen et al. reference (Desig. ID C1) has been inserted on the signed and initialed copy of the IDS.

Oath/Declaration

4. Applicant's arguments, see p10, filed on October 9, 2007, with respect to the objection of oath/declaration have been fully considered and are persuasive. The objection of oath/declaration has been withdrawn in view of new oath/declaration in the reply filed on October 9, 2007.

Objections Withdrawn

5. Applicant's arguments, see p10, filed on October 9, 2007, with respect to the objection of claims 21-24 have been fully considered and are persuasive. The objection of claims 21-24 has been withdrawn in view of cancelled claims 21-24 in the reply filed on October 9, 2007.

Rejections Withdrawn

6. The rejection of claim 8 has been withdrawn in view of amended claim 8 in the reply filed on October 9, 2007.

7. The following rejections have been withdrawn in view of amended claim 1 in the reply filed on October 9, 2007:

- Rejection of claims 1, 11, 12, and 16 under 35 U.S.C. 102(b) as being anticipated by Webb et al. (WO 97/46256, Dec. 11, 1997);
- Rejection of claims 1-3, 6, 7, 11, 15, and 16 under 35 U.S.C. 102(a) and 102(e) as being anticipated by Brown et al. (U.S. PG Pub. No. US 2003/0044389 A1, Mar. 6, 2003 and Filed on July 2, 2002);
- Rejection of claims 2-7 and 15 under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (WO 97/46256, Dec. 11, 1997) in view of Taylor (U.S. Patent No. 6,103,479, Aug. 15, 2000);
- Rejection of claims 8, 9, and 17 under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (WO 97/46256, Dec. 11, 1997) in view of Tom-Moy et al. (U.S. Patent No. 6,235,488, May 22, 2001);
- Rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (WO 97/46256, Dec. 11, 1997) in view of Abraham et al. (*J. Immunol.*, 20014, Vol. 167, pp5193-5201) and Mikesell et al. (U.S. PG Pub. No. US 2002/0095024, Filed on June 6, 2001);
- Rejection of claims 19, 20, 22, and 25 under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (WO 97/46256, Dec. 11, 1997) in view of Butler et al. (*J. Immunol.*, Oct. 2002, Vol. 169: 3700-3709);

- Rejection of claims 19, 20, 22, and 25 under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (WO 97/46256, Dec. 11, 1997) in view of Lehmann et al. (U.S. Patent No. 5,939,281, Aug. 17, 1999);
- Rejection of claim 21 under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (WO 97/46256, Dec. 11, 1997) in view of Butler et al. (*J. Immunol.*, Oct. 2002, Vol. 169: 3700-3709) as applied to claim 19 above, and further in view of Taylor (U.S. Patent No. 6,103,479, Aug. 15, 2000);
- Rejection of claim 21 under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (WO 97/46256, Dec. 11, 1997) in view of Lehmann et al. (U.S. Patent No. 5,939,281, Aug. 17, 1999) as applied to claim 19 above, and further in view of Taylor (U.S. Patent No. 6,103,479, Aug. 15, 2000);
- Rejection of claim 23 under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (WO 97/46256, Dec. 11, 1997) in view of Butler et al. (*J. Immunol.*, Oct. 2002, Vol. 169: 3700-3709) as applied to claim 19 above, and further in view of Tom-Moy et al. (U.S. Patent No. 6,235,488, May 22, 2001); and
- Rejection of claim 23 under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (WO 97/46256, Dec. 11, 1997) in view of Lehmann et al. (U.S. Patent No. 5,939,281, Aug. 17, 1999) as applied to claim 19 above, and further in view of Tom-Moy et al. (U.S. Patent No. 6,235,488, May 22, 2001).

Specification

8. The use of the trademark CY™ (p28) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicant's assertion that there is no evidence that the term "CY" by itself or terms such as "Cy3" and "Cy5" are trademarks has been fully considered but is not found persuasive as Jackson ImmunoResearch Material Safety Data Sheet (October 18, 2005, West Grove, PA) indicates that CY is a trademark of Amersham Biosciences Limited. Therefore, the objection of the specification as set forth above has been maintained.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 2, 5, 11, 12, 16, 20, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (WO 97/46256, Dec. 11, 1997) in view of Rhode et al. (U.S. Patent No. 6,232,445, May 15, 2001) and Lehmann et al. (U.S. Patent No. 5,939,281, Aug. 17, 1999).

Webb et al. teaches an array (see entire document) comprising a substrate (support, p49, lines 7-18) and a plurality of MHC molecules complexed with antigen-

derived peptides (p18, lines 9-17 and p50, line 1-p51, line 25) immobilized in spatially distinct areas on the substrate (wells of microtiter plates, p80, lines 24-31). Webb et al. further teaches that activation of T-cells is characterized by proliferation of the responsive T cell population coordinated with the selective production of cytokines (p16, lines 28-32). With respect to claim 20, Webb et al. teaches that the different cytokine profiles such as IL-2, IL-4, Il-5, IL-10, and IFN-γ characterize functional phenotypes of type 1 and type 2 T-cells (p16, lines 8-23).

With respect to claims 11 and 12, Webb et al. teaches an array, further comprising costimulatory molecules immobilized in the spatially-distinct areas on the substrate (p49, lines 7-14), wherein the costimulatory molecules are costimulatory antibodies (p21, line 27-p22, line 6).

With respect to claim 16, Webb et al. teaches an array, wherein the MHC molecules comprise class II MHC molecules (p18, lines 20-30).

However, Webb et al. is silent on disclosing that the each group of spatially distinct areas comprises a plurality of different MHC-peptide complexes and that the array, further comprises anti-factor antibodies specific for secreted factors, immobilized spatially-distinct areas on the substrate.

With respect to claims 1 and 2, Rhode et al. teaches that MHC complexes can be used to screen immune cells such as T-cells expressing a desired target structure in vitro (see entire document, particularly column 4, lines 24-26). A wide variety of peptides can be presented for interaction with T-cells (i.e. a library of different peptides can be linked to a MHC molecule for presentation of T-cells, column 5, lines 11-17).

With respect to claim 5, Rhode et al. further teaches that an array of MHC complexes can be formed on a substrate such as 96-well plates (column 55, lines 45-51) and MHC molecules are selected from Class I MHC molecules, Class II MHC molecules, or Class I and Class II MHC molecules (column 3, lines 36-45).

With respect to claims 1 and 25, Lehmann et al. teaches a method of detecting secreted cytokines by activated T-cells using cytokine capture assay (see entire document, particularly, column 3, lines 14-36). The cytokine capture assay of Lehmann et al. involves plating both the activating molecules (test antigen peptide) co-incubated with immobilized cytokine capture antibodies (column 3, lines 14-36).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ plurality of different MHC-peptide complexes of Rhode et al., which are formed by a MHC molecule complexed with a library of different peptides, in the array of Webb et al. in order to screen T cells expressing a desired target structure in vitro. The advantage of screening T cells for their interaction with a plurality of different peptides complexed to a MHC molecule provides the motivation to combine teachings of Webb et al. and Rhode et al. with a reasonable expectation of success. In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to include anti-factor antibodies specific for secreted factors co-immobilized on the spatially-distinct areas of the substrate with activating molecules as taught by Lehmann et al. in the array of Webb et al. in order to perform cytokine capture assay for detecting secreted cytokines by the activated T-cells. The advantage of allowing T-cell activation and capturing of the secreted cytokines following the activation in the same

area of the substrate provides the motivation to combine teachings of Webb et al. and Lehmann et al. with a reasonable expectation of success as the use of co-immobilized MHC molecules complexed with antigen-derived peptides and anti-factor antibodies specific for secreted factors would eliminate additional steps of supernatant harvesting and transferring of the supernatant to another substrate for cytokine detection assay necessary to determine cytokine profile of the activated T-cell populations.

13. Claims 3, 4, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (WO 97/46256, Dec. 11, 1997) in view of Rhode et al. (U.S. Patent No. 6,232,445, May 15, 2001) and Lehmann et al. (U.S. Patent No. 5,939,281, Aug. 17, 1999) as applied to claim 1 above, and further in view of Taylor (U.S. Patent No. 6,103,479, Aug. 15, 2000).

Webb et al. in view of Rhode et al. and Lehmann et al. teaches an array comprising a substrate and an array of MHC molecules complexed with antigen-derived peptides and costimulatory antibodies immobilized in spatially distinct areas on the substrate as set forth in item 12 above. However, Webb et al. in view of Rhode et al. and Lehmann et al. fails to teach an array, wherein the spatially distinct areas are all surrounded by a single hydrophobic barrier.

With respect to claims 3-7, Taylor teaches arrays for simultaneous analysis of multiple types of cell interactions (see entire document, particularly, column 6, lines 40-47). The arrays of Taylor encompass arrays that comprise identical cell types that can be treated with a combinatorial of distinct compounds (different specific cell binding

molecules) or a combinatorial cell types that can be treated with one or more compounds (the same specific cell binding molecules, column 6, lines 48-55). The micro-patterned chemical array comprises a base (substrate), which is treated to produce a hydrophobic surface across which are dispersed at regular intervals of hydrophilic spots or wells (spatially-distinct areas on the substrate, column 8, lines 34-37). The cells are bound only in the wells, because the specific chemical environment in the wells, in conjunction with the hydrophobic environment surrounding each of the wells, permits the selective binding of the cells to the wells only (column 11, lines 64-67). Modification of wells with specific cell binding molecules (immobilized specific cell binding molecules) permits selective binding of cells to specific wells (column 12, lines 1-3).

With respect to claims 6 and 7, Taylor teaches that the substrate comprises glass, which is optically transparent, or silicon (column 8, lines 34-40).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ the substrate (glass or silicon) of Taylor, which includes all the spatially-distinct areas surrounded by a single hydrophobic barrier and having either one type of compounds (the same MHC molecules) or a combinatorial of distinct compounds (different MHC molecules) in the array of Webb et al. in view of Rhode et al. and Lehmann et al. in order to conduct simultaneous analysis of multiple types of cell interactions. The advantage of using substrate, which allows selective binding of the cells of interest to the spatially-distinct areas only and simultaneous analysis of multiple types of cell interactions provides the motivation to employ the substrate of Taylor in the

array of Webb et al. in view of Rhode et al. and Lehmann et al. with a reasonable expectation of success as the substrate of Taylor can be used for a variety of cell interactions including lymphocytes such as T-cells.

14. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (WO 97/46256, Dec. 11, 1997) in view of Rhode et al. (U.S. Patent No. 6,232,445, May 15, 2001) and Lehmann et al. (U.S. Patent No. 5,939,281, Aug. 17, 1999) as applied to claim 1 above, and further in view of Tom-Moy et al. (U.S. Patent No. 6,235,488, May 22, 2001).

Webb et al. in view of Rhode et al. and Lehmann et al. teaches an array comprising a substrate and an array of MHC molecules complexed with antigen-derived peptides and costimulatory antibodies immobilized in spatially distinct areas on the substrate as set forth in item 12 above. Webb et al. in view of Rhode et al. and Lehmann et al. further teaches that biotinylated MHC molecules can be immobilized on the avidin-coated substrate via biotin-avidin linked interactions with the substrate (p81, lines 10-16). However, Webb et al. fails to teach that streptavidin can be used in place of avidin.

With respect to claims 8 and 9, Tom-Moy et al. teaches that streptavidin can be a substitute for avidin since it has similar biotin-binding properties (see entire document, particularly column 4, lines 62-63).

Therefore, Webb et al. in view of Rhode et al. and Lehmann et al. meets the limitations of claims 8 and 9 except that it employs avidin rather than streptavidin to coat

the substrate surface for immobilization of biotinylated MHC molecules. However, because these two elements were art-recognized equivalents at the time of the invention in the specific binding applications, where it is immaterial whether the avidin or streptavidin is used to bind to a biotin, one of ordinary skill in the art at the time of the invention would have found it obvious to substitute streptavidin for the avidin of Webb et al. in view of Rhode et al. and Lehmann et al.

15. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (WO 97/46256, Dec. 11, 1997) in view of Rhode et al. (U.S. Patent No. 6,232,445, May 15, 2001) and Lehmann et al. (U.S. Patent No. 5,939,281, Aug. 17, 1999) as applied to claims 1, 11, and 12 above, and further in view of Abraham et al. (*J. Immunol.*, 20014, Vol. 167, pp5193-5201) and Mikesell et al. (U.S. PG Pub. No. US 2002/0095024, Filed on June 6, 2001).

Webb et al. in view of Rhode et al. and Lehmann et al. teaches an array comprising a substrate and an array of MHC molecules complexed with antigen-derived peptides and costimulatory antibodies immobilized in spatially distinct areas on the substrate as set forth in item 12 above. Webb et al. further teaches the costimulatory molecules include ICAM's (ICAM-1, ICAM-2, and ICAM-3, p72, line 14-p74, line 20). Activation of T cells is characterized by proliferation of the responsive T cell population coordinated with the selection of cytokines (p16, lines 28-32). However, Webb et al. fails to teach an array, wherein the costimulatory antibodies bind specifically to CD11a.

Abraham et al. teaches that integrin LFA-1 serves as an accessory molecule in T cell activation (see entire document). The primary pathway whereby engagement of LFA-1 through its ligand ICAM-1 up-regulates IL-2 gene expression through enhanced IL-2 transcription (Abstract). Further, a number of anti-LFA-1 Abs has agonist/costimulatory activity such as anti-CD11a mAb (p5197, right column).

Mikesell et al. teaches that a first signal mediated by foreign antigens presented by MHC complexes causes T-cell entry into the cell cycle and a second signal, termed costimulation, causes cytokine production and T-cell proliferation (p1, paragraph [0003]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include anti-CD11a antibody of Abraham et al. as a costimulatory antibodies in the array of Webb et al. in view of Rhode et al. and Lehmann et al. in order to provide costimulatory signal in addition to the antigenic signal of the MHC molecules complexed with antigen-derived peptides necessary for production of cytokines and T-cell proliferation, which can be used to detect T-cell activation/responsiveness. The advantage of delivering necessary costimulatory signal for T-cell characterization provides the motivation to combine teachings of Webb et al. in view of Rhode et al. and Lehmann et al. and Abraham et al. with a reasonable expectation of success as Mikesell et al. teaches that a first signal mediated by foreign antigens presented by MHC complexes causes T-cell entry into the cell cycle and a second signal, termed costimulation, causes cytokine production and T-cell proliferation. Further, Webb et al. et al. in view of Rhode et al. and Lehmann et al. meets the

limitations of claim 13 except that it employs an ICAM's rather than anti-CD11a antibodies as costimulatory molecules. However, because these two elements were art-recognized equivalents at the time of the invention in the T-cell immunology arts, where it is immaterial whether the ICAM's or anti-CD11a antibodies are used to provide costimulatory signal to T-cells, one of ordinary skill in the art at the time of the invention would have found it obvious to substitute anti-CD11a antibodies for the ICAM's of Webb et al. in view of Rhode et al. and Lehmann et al.

Response to Arguments

16. Applicant's arguments with respect to claims 1-14, 16, 20, and 25 have been considered but are moot in view of the new ground(s) of rejection.

Since the prior art fulfills all the limitations currently recited in the claims, the invention as currently recited would read upon the prior art.

Conclusion

17. No claim is allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Unsu Jung/
Unsu Jung, Ph.D.
Patent Examiner
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